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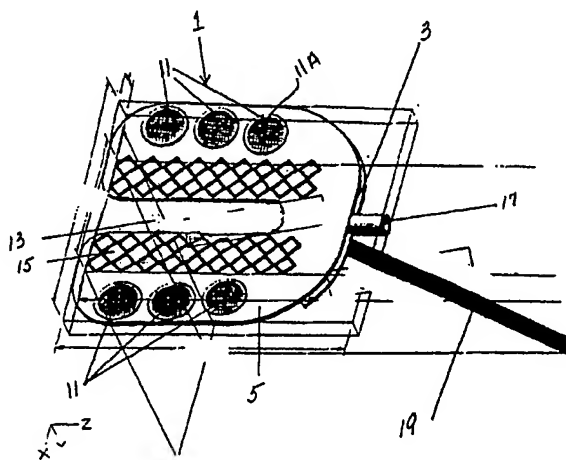
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(54) Title: TISSUE STABILIZER



(57) Abstract: A tissue stabilizer is disclosed that comprises a malleable planar foot integrated into a flexible membrane and is useful for stabilizing tissue such as the heart while performing surgery thereon. The malleable planar foot has an open central region and a rigid arm connected to the foot. The membrane integrated with the foot has a shape approximating the foot, a lower section having a bottom surface for contacting the tissue to be stabilized, and an upper section opposite the lower section. The membrane has an inner chamber in fluid communication through an opening with a plurality of suction ports on the bottom surface. An outlet port connects the inner chamber and suction ports to a negative pressure source. The tissue stabilizer has a centrally-located open region through which the tissue to be stabilized can be accessed and is designed so that when the bottom surface of the membrane is positioned on a tissue to be stabilized and a negative pressure is applied to the outlet port, the bottom surface tends to conform to the surface contour of the tissue to be stabilized through the action of suction by the ports and compression by the foot.

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TISSUE STABILIZER

1

2 **Cross Reference**

3 This patent application claims priority to U.S. provisional patent application
4 60/182,048, filed February 11, 2000 and is a continuation in-part thereof.

5

6 **Field of the Invention**

7 This invention relates to a surgery assistance device that stabilizes tissue to be
8 operated on by a combination of suction and compression.

9

10 **Background**

11 When surgeons perform a surgical procedure on a tissue it is often important
12 to stabilize the tissue so that the area that is being operated on is stable to ensure the
13 accuracy of the surgeon's work. This is particularly important when operating on an
14 internal organ such as the heart, whether a beating heart or a stopped heart. The tissue
15 needs to be stabilized in a manner that exposes the area being operated on to the
16 surgeon and needs to be easily used by the assistant whether such a person is another
17 doctor or a nurse. The device of this invention is designed to give improved
18 stabilization especially to a beating heart with motion reduction of the tissue in the X,
19 Y, and Z directions.

20

21

SUMMARY OF THE INVENTION

22 One aspect of this invention is a tissue stabilizer that comprises a malleable
23 planar foot integrated into a flexible membrane. The malleable planar foot has an
24 open central region and a rigid arm connected to the foot. The membrane integrated
25 with the foot has a shape approximating the foot, a lower section having a bottom
26 surface for contacting the tissue to be stabilized, and an upper section opposite the
27 lower section. The membrane has an inner chamber in fluid communication through
28 an opening with a plurality of suction ports on the bottom surface. An outlet port
29 connects the inner chamber and suction ports to a negative pressure source. The
30 tissue stabilizer has a centrally-located open region through which the tissue to be
31 stabilized can be accessed and is designed so that when the bottom surface of the
32 membrane is positioned on a tissue to be stabilized and a negative pressure is applied
33 to the outlet port, the bottom surface tends to conform to the surface contour of the

1 tissue to be stabilized through the action of suction by the ports and compression by
2 the foot. A surgeon is then able to operate on the tissue through the open region.

3 Another aspect of this invention is a tissue stabilizer that comprises a flexible
4 membrane suitable for integration with a malleable planar foot having a central access
5 opening. The membrane comprises a lower section having a bottom surface for
6 contacting the tissue to be stabilized and a top section opposite the lower section.
7 Together the sections form an inner chamber in the membrane. A plurality of suction
8 ports are located on the bottom surface, each suction port being in fluid
9 communication with the chamber through an opening. An outlet port is in fluid
10 communication with the inner chamber and suction ports and can be connected to a
11 negative pressure source. The membrane has a centrally-located open region through
12 which the tissue to be stabilized can be accessed and a sleeve between the top and
13 bottom sections designed to receive the malleable planar foot, which foot has an
14 extension on each side of the central region. When the planar foot is inserted into the
15 sleeve, the membrane and foot may be positioned on a tissue to be stabilized, and a
16 negative pressure is applied to the outlet port. The bottom surface conforms to the
17 surface contour of the tissue to be stabilized through the action of the suction ports
18 and compression by the foot.

19 Still another aspect of the invention is a method for stabilizing tissue. The
20 method comprises positioning the tissue stabilizer of this invention on the tissue to be
21 stabilized, then attaching a negative pressure source to the outlet port and providing
22 compressive force to the foot through the rigid arm for a time sufficient to conform the
23 proximal surface of the tissue stabilizer to the tissue area. After the tissue stabilizer
24 has been placed upon the tissue, an operation may be performed on the tissue through
25 the central open region of the foot and membrane. The stabilizer comprises a
26 malleable, planar foot having a central opening, a rigid arm connected to the foot, and
27 a membrane integrated with the foot. The membrane has a shape approximating the
28 foot, a lower section having a bottom surface for contacting the tissue to be stabilized,
29 and a top section opposite the bottom section. An inner chamber in the membrane is
30 in fluid communication with a plurality of suction ports on the bottom surface and
31 with an outlet port for connecting to a negative pressure source. The stabilizer has a
32 centrally-located open region through which the tissue to be stabilized can be
33 accessed and the stabilizer is designed so that when the bottom surface of the
34 membrane is positioned on a tissue to be stabilized and a negative pressure is applied

1 to the outlet port, the bottom surface conforms to the surface contour of the tissue to
2 be stabilized through the action of suction and compression.

3 A further aspect of the invention is a process for making the tissue stabilizer of
4 this invention using an injection molding technique. An appropriate mold is prepared
5 and provided with removable mandrels for the inner chamber and the outlet port of
6 the membrane. The foot and connecting rod are positioned with the mold to be
7 integrated into the membrane. A polymeric material is injected into the mold and
8 cured. The mandrels are removed and the upper section and lower section adhered to
9 form the chamber.

10 Other aspects of the invention will be apparent to one of skill in the art upon
11 reading the following specification and claims. Details of the invention are discussed
12 hereinafter.

13

14 **BRIEF DESCRIPTION OF THE DRAWINGS**

15 Figure 1 is a perspective view of a representative device of this invention
16 showing the bottom side of the device.

17 Figure 2 is a top view of the topside of a representative device of this
18 invention.

19 Figure 3 is a front view of a representative device shown in Figure 2 along line
20 4 - 4'.

21 Figure 4 is a bottom view of a representative device of this invention.

22 Figure 5 is a side perspective view of the internal chamber of a representative
23 device of this invention.

24 Figure 6 is a close-up side perspective view of the right-hand region of the
25 internal chamber depicted in Figure 5.

26 Figure 7 is an end view of a representative device of this invention taken along
27 line A-A' of Figure 4.

28 Figure 8 is a top view of a representative device of this invention.

29 Figure 9 is a cross-sectional view taken along lines AC-AC in Figure 8.

30 Figure 10 is a cross-sectional view taken along lines AD-AD of Figure 8.

31 Figure 11 is an end view taken along lines AB-AB in Figure 8.

32 Figure 12 is a cross-sectional downward view of a representative example of a
33 device of this invention along lines AE-AE in Figure 11.

1 Figure 13 is a bottom view of a representative device of this invention and
2 shows the surface opposite that shown in Figure 8.

3 Figure 14 is a rear view of a representative device of this invention shown in
4 Figure 13 taken along line AF-AF.

5 Figure 15 is a three-dimensional perspective of the bottom side of a device of
6 this invention wherein there are a total of four suction ports on the bottom of the
7 device.

8

9 **DETAILED DESCRIPTION OF SPECIFIC EMBODIMENTS**

10 **Overview**

11 The device of this invention readily is used in open-heart surgery and in
12 surgery on other tissues and organs. The tissue stabilizer is a combination of
13 compression and suction forces that are applied to the tissue, particularly a beating
14 heart, in the stabilization process. In functioning to stabilize the tissue of a beating
15 heart, for example, during anastomosis, the forces transmitted from the beating heart
16 pass through the separate zones of suction and compression thus damping those forces
17 and minimizing the motion at the anastomotic site. The amount of compression force
18 required to stabilize the epicardial tissue at the anastomotic site is reduced, thus
19 minimizing trauma, without introducing additional trauma due to the addition of
20 suction. The adherence of the device to the epicardial tissue aids preventing
21 movement, or drift, away from the anastomotic site.

22

23 **Characteristics Of The Device Of This Invention**

24 One aspect of this invention is a tissue stabilizer that comprises a malleable
25 planar foot integrated into a flexible membrane. The malleable planar foot has an
26 open central region and a rigid arm connected to the foot. The membrane integrated
27 with the foot has a shape approximating the foot, a lower section having a bottom
28 surface for contacting the tissue to be stabilized, and an upper section opposite the
29 lower section. The membrane has an inner chamber in fluid communication through
30 an opening with a plurality of suction ports on the bottom surface. An outlet port
31 communicates with the inner chamber and suction ports and is connectable to a
32 negative pressure source. The tissue stabilizer has a centrally-located open region
33 through which the tissue to be stabilized can be accessed and is designed so that when
34 the bottom surface of the membrane is positioned on a tissue to be stabilized and a

1 negative pressure is applied to the outlet port, the bottom surface tends to conform to
2 the surface contour of the tissue to be stabilized through the action of suction by the
3 ports and compression by the foot. A surgeon is then able to operate on the tissue
4 through the open region.

5 Turning now to Figure 1, one can see a representative tissue stabilizer shown
6 in perspective as 1. The stabilizer has a membrane shown as 3 with an inner chamber
7 (not shown) in the interior of the device formed by the upper and lower sections of the
8 device. The stabilizer has a bottom surface 5 of the lower section and a top surface 7
9 of the upper section (not shown in Figure 1). The bottom surface is the surface that
10 contacts the tissue to be stabilized. The inner chamber is not shown in Figure 1
11 because the view is an exterior view. On the bottom surface of the stabilizer one sees
12 a plurality of suction ports 11 around the perimeter. While Figure 1 shows a total of 6
13 suction ports, the number may vary between 2 and 10, preferably there are 4 or 6
14 ports, equally distributed as shown. Each port is in fluid communication with the
15 inner chamber that leads to an outlet port 17. The suction ports may be covered by a
16 mesh or screen as shown as 11A and are preferably shaped like the suction ports of an
17 octopus, *i.e.* they are circular, although other shapes such as squares, ovals, etc. may
18 be employed. The outlet port 17, which is in fluid communication with the inner
19 chamber and the suction ports, is designed to be connected to a negative pressure
20 source. Thus, a vacuum is applied to draw air out of the inner bladder and create
21 suction along the suction ports.

22 The bottom surface shown also has at least a portion (shown as an area 15)
23 that has been modified to aid in maintaining bottom surface against the tissue being
24 stabilized and preventing slippage of the stabilizer, *i.e.* the modification is such that
25 the movement relative to the tissue surface is reduced. The modification may be done
26 by texturing the surface with cross-hatching as shown in Figure 1, providing rows of
27 dimples or bumps, or other designs that reduce movement relative to the tissue
28 surface, *e.g.* stippling. Alternatively, the surface may be modified by placing a
29 physiologically-acceptable adhesive on it to assist in adhering the lower surface to the
30 tissue to be stabilized. While the arrangement shown in Figure 1 shows the modified
31 area immediately around the central opening 13 with the suction ports around the
32 perimeter of the lower surface, the ports may be located around the central opening
33 directly under the planar foot with the modified area (as indicated by the cross-
34 hatching) located around the perimeter. It is preferred, however, that the malleable

1 planar foot be positioned so that the bottom planar surface of the foot does not press
2 down on the suction ports. While Figure 1 shows only a portion of the bottom surface
3 modified, nearly the entire bottom surface can be modified. Preferably, the bottom
4 surface of the suction ports are not textured, as this could adversely affect the suction
5 against the tissue.

6 If the bottom surface is modified using a physiologically acceptable adhesive,
7 various adhesive approaches may be used. The adhesive maybe applied to the tissue
8 and the bottom surface placed on the tissue, *e.g.* a heart. Alternatively, and
9 preferably, the adhesive is applied to the bottom surface prior to the application of the
10 device to the tissue to be stabilized. The adhesive must be sufficiently biocompatible
11 to dissipate relatively harmlessly in the body fluids or be removable with minimal
12 difficulty. Water soluble biocompatible adhesive are known and used in various
13 surgical and medical procedures. Hydrogel polymers of hydroxy ethylcellulose or
14 hydroxy melthocelulose and hydrogel copolymers of these two are examples.
15 Polymers with acrylic acid and acrylic esters are also known to be useful
16 biocompatible adhesives. Polyvinyl alcohol is another water-soluble adhesive that
17 may be used. If the device has a bottom surface that is made of a silicon rubber, a
18 biocompatible silicon rubber having a durometer rating of approximately zero (which
19 means that it is nearly a liquid) is useful in the invention.

20 The connector arm 19 is connected to the inner malleable foot 21, which is not
21 shown in Figure 1. The inner malleable foot is designed to provide compression,
22 which acts in conjunction with and adjacent to the suction ports on the bottom
23 surface, to maintain contact with the surface of the tissue. Thus, the device in
24 operation is placed on the tissue to be stabilized, for example a beating heart, and the
25 stabilization of the tissue adjacent to the tissue targeted for stabilization occurs
26 through compression while the stabilization of the tissue adjacent to the tissue under
27 compression is stabilized via suction provided by ports 11. This creates varying zones
28 of stabilization proximal to the target tissue by gradually isolating the movements or
29 forces transmitted from unstabilized tissue. Portions of the tissue are drawn into the
30 ports due to the vacuum that is drawn through out at port 17. With this combination,
31 a surgeon can position the device to stabilize the desired tissue so that the central open
32 region 13 is arranged to expose part of the tissue to be operated upon. While the
33 preferred design of the planar foot shown in Figure 1 is basically a "U" shaped design,
34 it may be circular, rectangular, etc. design as well, so that the open region would be

1 the central part with the malleable foot surrounding it and the suction ports located at
2 the perimeter not directly beneath the foot.

3 It is also possible to provide the device as a family of products which are
4 geometrically configured or sized and specifically optimized for the tissue or region
5 targeted for stabilization. The malleable foot, is molded to approximately conform to
6 the tissue surface being stabilized.

7 Turning now to Figure 2, one sees a top view of the tissue stabilizer 1 of this
8 invention having the top surface 7 of the upper section. The membrane is generally
9 shown as 3 with the connector arm 19 connected to the inner malleable foot 21. In
10 this particular case, only a portion of the malleable foot is shown in the exterior with a
11 dotted line showing the extent of the malleable foot in the interior of the membrane.
12 The foot may fit into the membrane through a sleeve, which would allow the foot to
13 be removed from the sleeve and placed into another membrane of similar design.
14 Alternatively, the malleable foot could be injection molded into the membrane design
15 so that the malleable foot is not removable from the bladder. Thus, the material,
16 which coats the foot, would permanently coat it so that it would not slip out of a
17 sleeve.

18 The malleable foot is manufactured out of a ductile metal or polymeric
19 material by either a stamping process or typical machining practice. The shape can be
20 adjusted once associated with the membrane. The connector arm is brazed, soldered,
21 bonded, or welded onto the malleable foot. The assembled portion above is inserted
22 into a mold and liquid silicone is injection molded around it to form the bladder as
23 discussed hereinafter.

24 The device finds particular application in beating heart surgery in animals and
25 is particularly useful for the cardiac surgeon in his or her armamentarium for coronary
26 revascularization in humans. The device allows a surgeon to improve the patient care
27 and perform beating heart surgery in a controlled fashion with reproducibly good
28 results. The connector arm 19, as mentioned before, is used to provide the
29 compression to push down and immobilize the epicardium around the target tissue to
30 be worked upon. Once the tissue stabilizer is gently placed down on the tissue to be
31 stabilized, the suction then pulls up on the epicardium making the tissue around the
32 target vessel taut. The connector arm may be held by an assistant during the operation
33 or can be connected to a stabilizer arm that is connected to the table or some other
34 stable part of the operating theater. For example, the connector arm 19 can be

1 attached to the adjustable arm of the Universal Stabilizer System manufactured by
2 Endoscopic Technologies. By utilizing this combined approach, the tissue is
3 stabilized, with motion in the X, Y and Z directions reduced significantly. The
4 connector arm can be pivoted at point 18 so that it has multiple plains of movement.
5 In Figure 2, the arrows show that it can move either right or left and is connected to
6 the malleable foot by a connecting pin. Alternatively, it could be connected through a
7 universal joint that could be tightened to keep it in place. This device is of various
8 sizes and can be used multi-vessel target access easily. It allows for easy surgeon and
9 assistant flexibility and is easily used by nurses in assisting in the operation.

10 Turning now to Figure 3, one sees an end view of the tissue stabilizer of this
11 invention viewed along line 4 - 4' in Figure 2. Here one can see the connector arm
12 19, which is connected at point 18 to the malleable foot 21. The bottom surface 5 is
13 shown having a suction port 11 and a textured area 15. The central open region is
14 shown as 13 but is not particularly noticeable because the figure is shown in two-
15 dimensional instead of three-dimensional. The upper or distal surface 7 is shown
16 being opposite of the bottom surface 5. The tissue surface on which the operation
17 would be carried out is shown as dotted line 22 and is slightly curved. Here the tissue
18 stabilizer has not been placed onto the surface as yet. The malleable foot can be
19 molded to follow the surface to be stabilized and the suction portion which extends in
20 part beyond the foot will then adapt to the surface and will draw the surface into the
21 suction port thus stabilizing the tissue in preparing it for the operation.

22 The materials that are particularly useful for the tissue stabilizer can be any of
23 those materials that are biologically acceptable to be used by surgeons in operations
24 on tissue, particularly operations on the heart. Thus, the malleable foot can be a
25 metallic material which can be deformed but which will maintain its form once it is
26 deformed. These include stainless steel, aluminum, and precious metals.
27 Alternatively, materials used for the malleable foot can be various plastics which are
28 maleable but which will retain their form once they are molded to the surface
29 configuration as desired. The material covering the malleable foot and comprising the
30 membrane will generally be any polymeric materials, which is suitable for contacting
31 tissue. This can include silicones, polyurethanes, polypropylene, polyethylene, and
32 the like. Sources for the material include those commercially available from sources
33 such as Dow, Bayer, UG and many others. Silicone is preferred, particularly silicone
34 with a durometer rating of about 50-100 Shore.

1 Turning now to Figure 4 one sees a view of the bottom of the device in this
2 invention. This is a perspective showing the device 30 generally in a bottom view
3 showing the bottom surface 47 of the lower section device. A suction port 31 is
4 defined by a circular ridge 32 and having a suction opening 33 leading to the suction
5 port and into the internal chamber discussed further in relation to Figure 5. Figure 4
6 is shown with six equivalent suction ports although the number could be greater or
7 lesser, as discussed herein. The suction ports 31 are shown as located around the
8 outer perimeter of the bottom surface of the device away from the central opening 34
9 and preferably not directly beneath the planar foot. A tapered region 35 preferably
10 surrounds central opening 34. The tapered region fits more closely to the surface of
11 the tissue to be worked on. Although not required there is a slight ridge 36 extending
12 around the perimeter defined area of the bottom. Figure 4 shows that the surface of
13 the bottom area is stippled or provided with slight bubble-like texture on the entire
14 bottom of the surface of the device. This stippling or texturing is a modification that
15 aids in preventing the movement of the device against the tissue on which it is used.

16 Turning now to Figure 5 one sees the top view of the internal portion of the
17 bottom section of the device. A suction opening 33 leads to the suction port 31 and a
18 channel 43 leads to the suction opening 33. The channel is defined by ridges 38
19 above the suction ports. In addition there is a further ridge 39 towards the back of the
20 lower section shown. The ridges 38 and 39 prevent the upper surface which is
21 laminated or molded to the lower section from collapsing on suction opening 33 and
22 preventing a negative pressure from being sustained. Thus when the upper surface is
23 molded to the lower section, a chamber 48 connects each of the suction ports 31 in
24 Figure 4 and the openings 33 are maintained opened. This advantageous design
25 ensures that the suction opening 33 stays open and does not have the upper surface
26 collapsing on the opening. In forming the chamber 48 a ridge 40 extends around the
27 perimeter of the footprint for receiving the maleable planar foot that is an integral part
28 of the device. The foot, as discussed before may be an integral part of the device and
29 molded with the device or it may be slipped into a sleeve which is formed between the
30 upper and lower sections of the device. The raised rear ridge 42 completes the
31 definition of the internal chamber 48 out of which the air is sucked. The ridge is
32 particularly valuable in the manufacturing process as will be discussed hereinafter.

33 Figure 6 is a close-up perspective view of the right-hand side of Figure 5.
34 Here one can see the ridges 38 above the suction port along with the rear ridge 39 to

1 prevent the upper surface from collapsing into the lumen. Channel 43 is defined by
2 the ridges 38 above the suction port. The rear ridge 42 and internal ridge 40 are
3 shown and further define the chamber.

4 Turning now to Figure 7 one sees the end-on view of the device shown in
5 Figure 4 along lines A-A' in Figure 6. The circular ridge 32 forms the suction port 31
6 and the central opening 34 is shown along with the tapered region 35 surrounding the
7 central opening. The outlet port connectable to the reduced pressure area or suction
8 area is shown as 45.

9 Turning now to Figure 8, the numerals used are the same as the numerals used
10 to designate the components of Figures 4-7. This is a top view of a device 30 of this
11 invention where the top surface 44 is seen. The suction outlet port 45 is provided that
12 allows the internal chamber (not shown) to be evacuated upon connection to a suction
13 pump, syringe, or other means to create a negative pressure. The edge 46 of the
14 bottom section is shown protruding around the top surface 44. The central opening
15 area is shown as 34.

16 Figure 9 shows a cross-sectional view of Figure 8 along line AC-AC, with the
17 top surface 44 and the bottom surface 47 of the lower section of the device 30. In this
18 cross-section view, one also sees the circular ridge 32 in profile which forms the
19 suction port 31 on the bottom surface 47 of the device 30. One also sees the suction
20 outlet port 45 along with the internal ridge 42 as shown in Figure 5. The planar foot
21 is not shown in this diagram.

22 Figure 10 is a cross-section view along lines AD-AD from Figure 8. This is
23 analogous to the internal perspective view of Figure 5. Here, the top surface 44 has a
24 region 41 for accepting the planar foot in the device. Suction outlet port 45 extends
25 through the upper surface 44 to the internal chamber 48 defined by the upper surface
26 44 and the lower section having bottom surface 47. A channel 43 through ridge 38
27 aids in forming the suction opening 33 for suction port 31.

28 Figure 11 is an end view along lines AB-AB in Figure 8. Here, one can see
29 the bottom surface 47 and the upper surface 44 of device 30. The suction outlet port
30 is shown as 45 with central opening shown as 34. The circular ridge 32 that defines
31 the suction port 31 protrudes from the lower surface 47.

32 Turning now to Figure 12, we see the cross-sectional view below the upper
33 surface 44 of Figure 11 along lines AE-AE. This view of Figure 12 is comparable to
34 the perspective view of Figure 5. Here, one can see the open section 34 which

1 exposes the portion of the tissue to be operated upon. A channel 43 runs through the
2 ridges 38 leading to opening 33 and into the suction port 31 on the bottom surface,
3 now shown. The rear ridge 39 assists in preventing the upper surface, not shown,
4 from collapsing to the lower portion of the chamber 48 to reach opening 33 and thus
5 affecting the suction of the device. The chamber 48 is further defined by the ridge 40
6 running around the perimeter of the device. It can be seen that if the upper surface 44
7 were placed upon the lower section of the device, a chamber 48 would be formed and
8 the ridges 42, 39, 38 and 40 will all cooperate to keep the upper surface 34 from
9 collapsing and closing chamber 48.

10 Figure 13 shows the reverse side of Figure 12 and is analogous to the
11 perspective drawing shown in Figure 4. Here one sees the opening 34 of the device
12 30 and further sees the suction opening 33 leading to the suction port 31 which is
13 defined by circular ridge 32. The lower surface 47 is shown as being stippled across
14 nearly the entire surface, a modification of the surface that helps prevent the
15 movement of the lower surface across the tissue being worked on. The beveled
16 region 35 is shown around the central portion 34 of the device 30.

17 Figure 14 is the view along lines AF-AF in Figure 13 of device 30 without the
18 planar foot and connecting end. The circular ridge 32 which is defining the suction
19 port within the circled ridge. The suction outlet port 45 is shown along with the upper
20 surface 44.

21 Figure 15 is analogous to Figure 4, with like numbers referring to like
22 components. The primary differences are that the device of Figure 15 has only four
23 total suction ports around the outer perimeter of the bottom surface (as compared to
24 six in Figure 4) and only portion of the bottom surface is shown as being modified
25 with texturing.

26 Having described the characteristics of the invention in detail, one can see that
27 an aspect of the invention can be summarized as a tissue stabilizer that comprises a
28 flexible membrane suitable for integration with a malleable planar foot having a
29 central access opening. The membrane comprises a lower section having a bottom
30 surface for contacting the tissue to be stabilized and a top section opposite the lower
31 section. Together the sections form an inner chamber in the membrane. A plurality
32 of suction ports are located on the bottom surface, each suction port being in fluid
33 communication with the chamber through an opening. An outlet port is in fluid
34 communication with the inner chamber and suction ports and can be connected to a

1 negative pressure source. The membrane has a centrally-located open region through
2 which the tissue to be stabilized can be accessed and a sleeve between the top and
3 bottom sections designed to receive the malleable planar foot, which foot has an
4 extension on each side of the central region. When the planar foot is inserted into the
5 sleeve, the membrane and foot may be positioned on a tissue to be stabilized, and a
6 negative pressure is applied to the outlet port. The bottom surface conforms to the
7 surface contour of the tissue to be stabilized through the action of the suction ports
8 and compression by the foot.

9 Another aspect of the invention can be viewed as a method for stabilizing
10 tissue. The method comprises positioning the tissue stabilizer of this invention on the
11 tissue to be stabilized, then attaching a negative pressure source to the outlet port and
12 providing compressive force to the foot through the rigid arm for a time sufficient to
13 conform the proximal surface of the tissue stabilizer to the tissue area. After the
14 tissue stabilizer has been placed upon the tissue, an operation may be performed on
15 the tissue through the central open region of the foot and membrane. The stabilizer
16 comprises a malleable, planar foot having a central opening, a rigid arm connected to
17 the foot, and a membrane integrated with the foot. The membrane has a shape
18 approximating the foot, a lower section having a bottom surface for contacting the
19 tissue to be stabilized, and a top section opposite the bottom section. An inner
20 chamber in the membrane is in fluid communication with a plurality of suction ports
21 on the bottom surface and with an outlet port for connecting to a negative pressure
22 source. The stabilizer has a centrally-located open region through which the tissue to
23 be stabilized can be accessed and the stabilizer is designed so that when the bottom
24 surface of the membrane is positioned on a tissue to be stabilized and a negative
25 pressure is applied to the outlet port, the bottom surface conforms to the surface
26 contour of the tissue to be stabilized through the action of suction and compression.

27

28 **Making The Device Of The Invention**

29 The device of this invention is made using injection molding techniques. The
30 molds are designed to mold the lower section to the top section in one injection
31 molding process. In a preferred aspect, the process also is designed to make the
32 planar foot an integral part of the device. By reference to Figures 1-15, one can
33 understand the process. In general, the steps are as follows: an injection mold is
34 prepared, having the general characteristics that will result in a device shown in

1 Figures 1-15. A removable mandrel that provides the internal design for chamber 48
2 provided in Figure 5 is placed within the injection molding equipment. A rod
3 defining injection port 45, which rod is removable, is placed within the injection
4 molding apparatus. The desired polymeric material is then injected into the mold with
5 the planar foot in place so that it is integrated into the mold. The polymer is allowed
6 to cure, the rod forming the outlet port is removed and the mandrel defining the inner
7 chamber is removed. Thereafter, an appropriate adhesive is applied to the outer edge
8 of the lower section along the ridge 42 and the edge 49 to adhere the upper section to
9 the lower section of the device and to form a relatively airtight chamber 48 as
10 discussed herein. Once the glue has cured, the device is ready to be used. The
11 adhesive that is particularly valuable for bonding the upper and lower surface at the
12 rear-end is an adhesive for silicon put out by General Electric Corporation of
13 Waterford, New York called RTV adhesive.

14 In the manufacturing of the device it is preferred that the device is injection
15 molded using an appropriate polymeric material that has a durometer rating that is in
16 the range of about 50-100 Shore, preferably about 60-90 Shore.

17 In general the width and length of device will be about 1 to 3 inches,
18 preferably about 1½ to 2 inches. The thickness of the membrane will be less than
19 about 0.5 inches, preferably about 0.25 inch, but more than about 0.1 inch. The
20 central opening may vary from about 0.2 to 0.8 inches with a particularly useful
21 opening being about 0.3 to 0.5 inches. Opening 33 may be anywhere from 0.05
22 inches to 0.1 inch, 0.063 being a particularly useful diameter of that opening. The
23 internal diameter of the suction port 31 formed by circular ridge 32 may be from 0.1
24 to 0.3, with 0.02 inches particularly valuable. The centers of each suction port 31
25 may be anywhere from 0.3 to 0.5 inches, with 0.345 being useful for a device having
26 3 ports and 0.4 being useful for a device having only 2 ports per side.

27 The invention now being fully described, it will be apparent to one of ordinary
28 skill in the art that many changes and modifications can be made thereto without
29 departing from the spirit or scope of the appended claims.

30 All publications and patent applications mentioned in this specification are
31 herein incorporated by reference to the same extent as if each individual publication
32 or patent application was specifically and individually indicated to be incorporated by
33 reference.

1 **THE SUBJECT MATTER CLAIMED IS:**

2

- 3 1. A tissue stabilizer that comprises
4 a malleable planar foot having an open central region;
5 a rigid arm connected to the foot;
6 a membrane integrated with the foot and having a shape approximating the
7 foot, a lower section having a bottom surface for contacting the tissue to be stabilized,
8 and an upper section opposite the lower section;
9 an inner chamber in the membrane;
10 a plurality of suction ports on the bottom surface, the suction ports in fluid
11 communication with the inner chamber through an opening;
12 an outlet port connecting the inner chamber and suction ports to a negative
13 pressure source; and
14 a centrally-located open region through which the tissue to be stabilized can be
15 accessed,
16 the stabilizer being designed so that when the bottom surface of the membrane
17 is positioned on a tissue to be stabilized and a negative pressure is applied to the outlet
18 port, the bottom surface tends to conform to the surface contour of the tissue to be
19 stabilized through the action of suction by the ports and compression by the foot.
20
21 2. The tissue stabilizer of claim 1, wherein the suction ports are located around
22 the outer perimeter of the bottom surface not directly beneath the malleable planar
23 foot.
24
25 3. The tissue stabilizer of Claim 1, wherein at least a portion of the bottom
26 surface is modified to reduce movement of the stabilizer relative to the tissue to be
27 stabilized.
28
29 4. The tissue stabilizer of Claim 3, wherein the bottom surface around the central
30 opening is textured.
31
32 5. The tissue stabilizer of Claim 3, wherein nearly all of the bottom surface is
33 textured.

34

- 1 6. The tissue stabilizer of Claim 3, wherein the modified bottom surface has a
2 biocompatible medical-grade adhesive on it.
3
- 4 7. The tissue stabilizer of Claim 1, wherein the shape of the foot and bladder is a
5 "U" shape.
6
- 7 8. The tissue stabilizer of Claim 1, wherein the shape of the foot and bladder is
8 adjusted to approximate the contours of the surface of the tissue to be stabilized.
9
- 10 9. The tissue stabilizer of Claim 1, wherein the tissue is of an internal organ.
11
- 12 10. The tissue stabilizer of Claim 1, wherein the membrane is made of a medical
13 grade, flexible polymeric material.
14
- 15 11. The tissue stabilizer of claim 10, wherein the membrane is a silicon polymer
16 having a durometer rating of 50 to 100 Shore.
17
- 18 12. The tissue stabilizer of Claim 1, wherein the distance between the bottom
19 surface and the top surface of the membrane is about 0.1 inch to about 0.5 inch, the
20 width of the tissue stabilizer is about 1.0 inch to about 3.0 inches, and the length of
21 the tissue stabilizer is about 1.0 inch to about 3.0 inches.
22
- 23 13. The tissue stabilizer of Claim 11, wherein the volume of the internal chamber
24 within the membrane is about 1500mm³ to about 24,000mm³.
25
- 26 14. The tissue stabilizer of Claim 1, wherein the surface area of the bottom surface
27 is about 1.0 inch to about 9.0 inches.
28
- 29 15. The tissue stabilizer of Claim 1, in combination with a negative pressure
30 source.
31
- 32 16. The tissue stabilizer of Claim 1, wherein the inner chamber has a series of
33 ridges protecting the opening leading to the suction port to prevent the upper section
34 from covering the opening and preventing the suction action during operation.

1

2 17. A membrane for aiding the stabilization of a tissue during an operation on
3 such tissue, which membrane comprises
4 a lower section having a bottom surface for contacting the tissue to be
5 stabilized;
6 a top section opposite the lower section;
7 at least one inner chamber in the membrane;
8 a plurality of suction ports on the bottom surface, each suction port being in
9 fluid communication with the chamber through an opening;
10 an outlet port connecting the inner chamber and suction ports to a negative
11 pressure source;
12 a centrally-located open region through which the tissue to be stabilized can be
13 accessed; and
14 a sleeve between the top and bottom sections designed to receive a malleable
15 planar foot having an extension on each side of the central region,
16 the membrane being designed so that when the planar foot is inserted into the
17 sleeve, the membrane and foot are positioned on a tissue to be stabilized, and a
18 negative pressure is applied to the port, the bottom surface conforms to the surface
19 contour of the tissue to be stabilized through the action of suction by the ports and
20 compression by the foot.

21

22 18. The membrane of Claim 17, wherein the plurality of suction ports are located
23 around the outer perimeter of the bottom surface away from the sleeve into which the
24 planar foot fits.

25

26 19. The membrane of Claim 17, wherein at least a portion of the bottom surface is
27 modified to reduce movement of the bladder relative to the tissue to be stabilized.

28

29 20. The membrane of Claim 19, wherein nearly all of the bottom surface is
30 textured.

31

32 21. The membrane of Claim 19, wherein the modified bottom surface has a
33 biocompatible medical grade adhesive on it.

34

1 22. The membrane of Claim 17, wherein the sleeve is designed to receive a "U"
2 shaped foot with an extension of the "U" on each side of the central opening.

3

4 23. The membrane of Claim 17, wherein after the foot is inserted into the
5 membrane, the shape of the bottom surface is adjusted to fit the contours of the
6 surface of the tissue to be stabilized.

7

8 24. The membrane of Claim 17, wherein the tissue is chosen from tissue of an
9 internal organ.

10

11 25. The membrane of Claim 17, made of a medical grade, flexible polymeric
12 material.

13

14 26. The membrane of Claim 24 made of a silicone polymer having a durometer
15 rating of about 50 to 100 Shore.

16

17 27. The membrane of Claim 17, wherein the distance between the bottom surface
18 and the top surface of the bladder is about 0.1 inch to about 0.5 inch, the width of the
19 tissue stabilizer is about 1.0 inch to about 3.0 inches, and the length of the tissue
20 stabilizer is about 1.0 inch to about 3.0 inches.

21

22 28. The membrane of Claim 17, wherein the volume of the chamber is about
23 1500mm³ to about 24,000mm³.

24

25 29. The membrane of Claim 17, wherein the surface area of the bottom surface is
26 about 1.0 square inch to about 9.0 square inches.

27

28 30. The membrane of Claim 17, in combination with a negative pressure source
29 and an inserted planar foot.

30

31 31. The membrane of Claim 17, wherein the inner chamber has a series of ridges
32 protecting the opening leading to the suction port to prevent the upper section from
33 covering the opening and preventing the suction action during operation.

34

- 1 32. A method for stabilizing tissue, which method comprises
- 2 (a) positioning a tissue stabilizer on the tissue to be stabilized, wherein the
- 3 tissue stabilizer comprises (i) a malleable, planar foot having a central opening; (ii) a
- 4 rigid arm connected to the foot; (iii) a membrane integrated with the foot and having a
- 5 shape approximating the foot, a lower section having a bottom surface for contacting
- 6 the tissue to be stabilized, and a top section opposite the bottom section; (iv) at least
- 7 one inner chamber in the membrane; (v) a plurality of suction ports on the bottom
- 8 surface, each suction port being in fluid communication with the inner chamber;
- 9 (vi) an outlet port for connecting the inner chamber and suction ports to a negative
- 10 pressure source; (vii) a centrally-located open region through which the tissue to be
- 11 stabilized can be accessed; and (viii) the stabilizer being designed so that when the
- 12 bottom surface of the membrane is positioned on a tissue to be stabilized and a
- 13 negative pressure is applied to the outlet port, the bottom surface conforms to the
- 14 surface contour of the tissue to be stabilized through the action of suction and
- 15 compression and
- 16 (b) attaching a negative pressure source to the outlet port and providing
- 17 compressive force to the foot through the rigid arm for a time sufficient to conform the
- 18 proximal surface of the tissue stabilizer to the tissue area.
- 19
- 20 33. The method of Claim 32, wherein the tissue is of an internal organ.
- 21
- 22 34. The method of Claim 33, wherein the tissue to be stabilized is heart tissue.
- 23
- 24 35. The method of Claim 32, wherein after the tissue stabilizer has been placed
- 25 upon the tissue, an operation is performed on the tissue through the centrally-located
- 26 open region of the foot and membrane.
- 27
- 28 36. The method of Claim 32, wherein the shape of the foot and membrane is a "U"
- 29 shape.
- 30
- 31 37. The method of Claim 32, wherein the suction ports are located around the
- 32 outer perimeter of the bottom surface not beneath the malleable planar foot.
- 33

1 38. The method of Claim 32, wherein at least a portion of the bottom surface
2 around the central opening is modified to reduce the movement of the stabilizer
3 relative to the tissue to be stabilized.

4
5 39. The method of Claim 38, wherein the modified area of the bottom surface is
6 coated with a light medical adhesive to allow it to lightly adhere to the tissue surface.

7
8 40. The method of Claim 38, wherein the modified area of the bottom surface is
9 textured.

10
11 41. The method of Claim 38, wherein nearly the entire bottom surface is textured.

12
13 42. A process for making the tissue stabilizer of Claim 1 using an injection
14 molding technique, which process comprises
15 preparing an appropriate mold provided with removable mandrels for the inner
16 chamber and the outlet port of the membrane,
17 position the foot and connecting rod with the mold to be integrated into the
18 membrane,
19 injecting a polymeric material into the mold,
20 curing the polymer,
21 removing the mandrels, and
22 adhering the upper section and lower section to form the chamber.

23

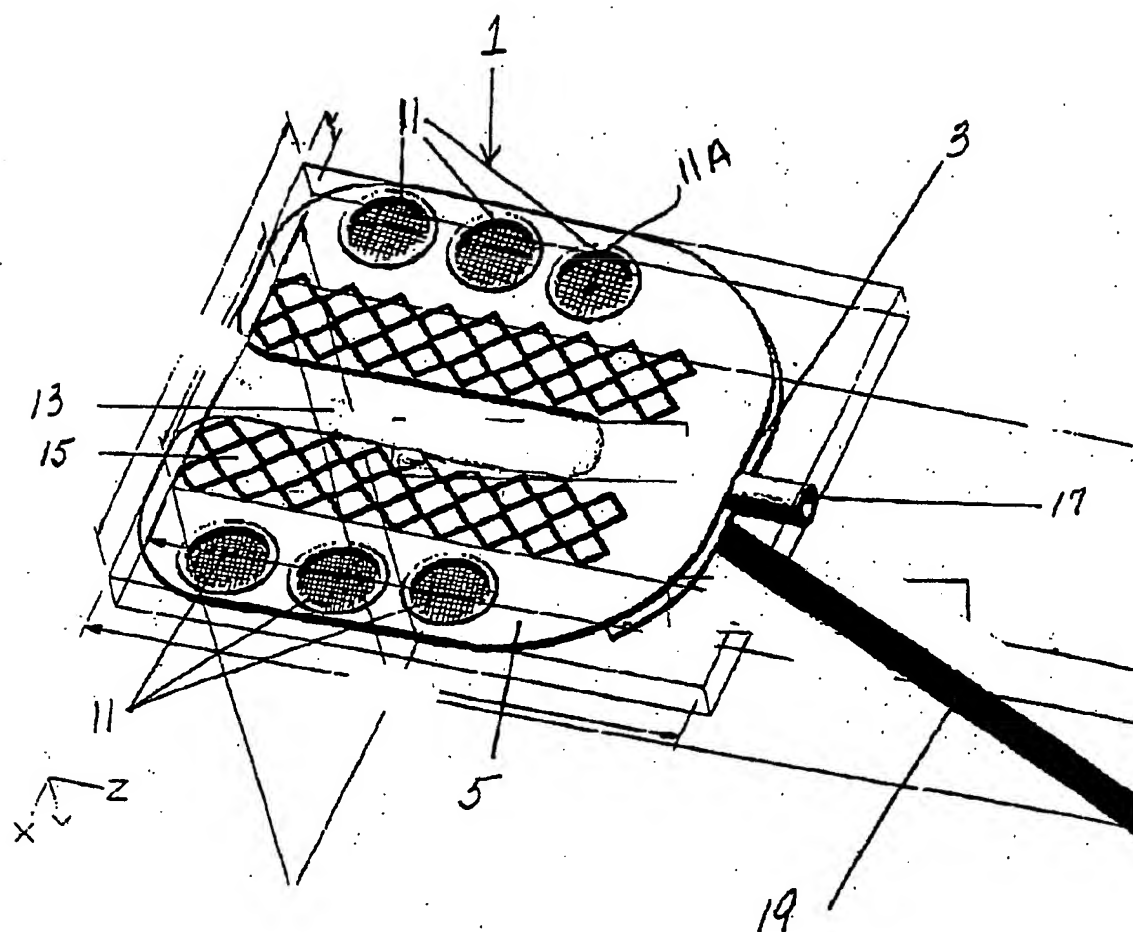


FIGURE 1

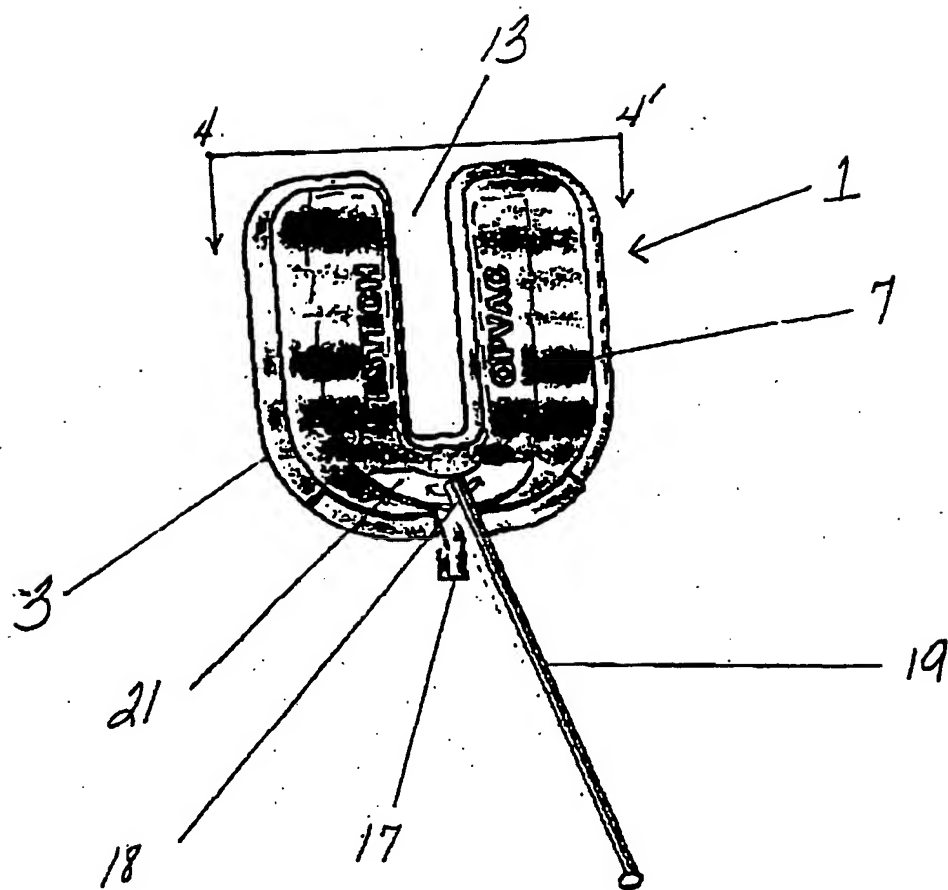


FIGURE 2

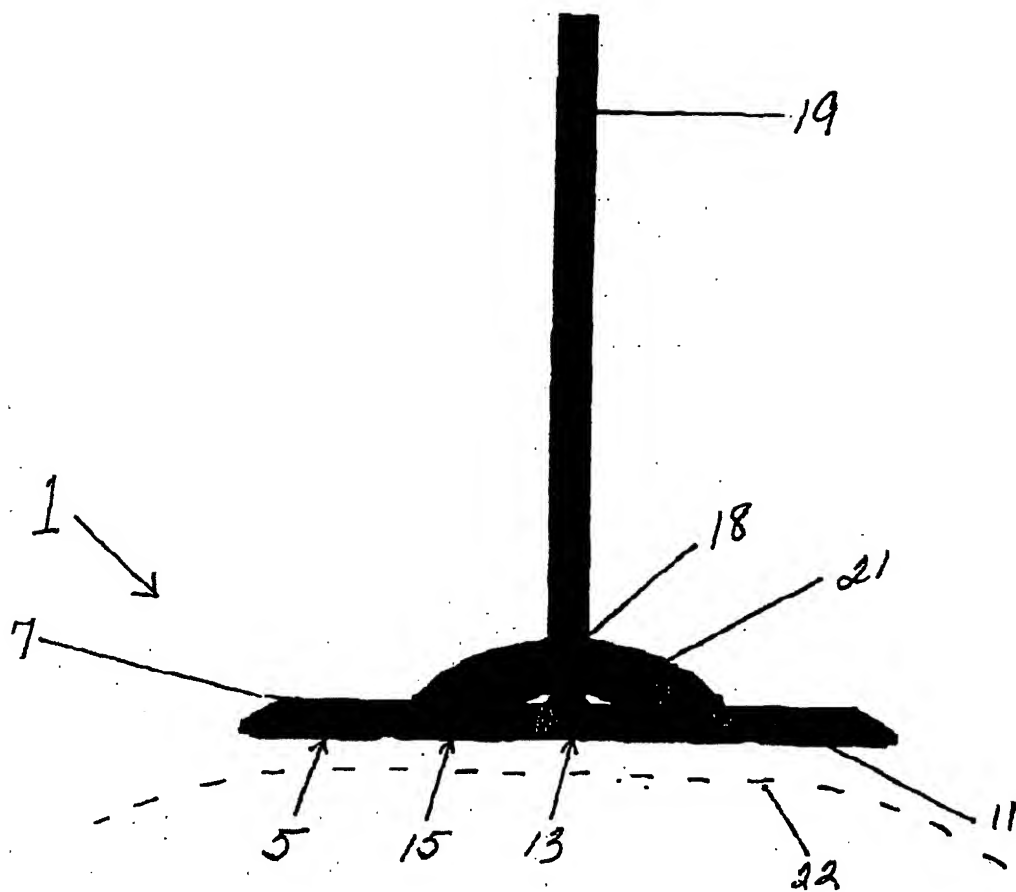


FIGURE 3

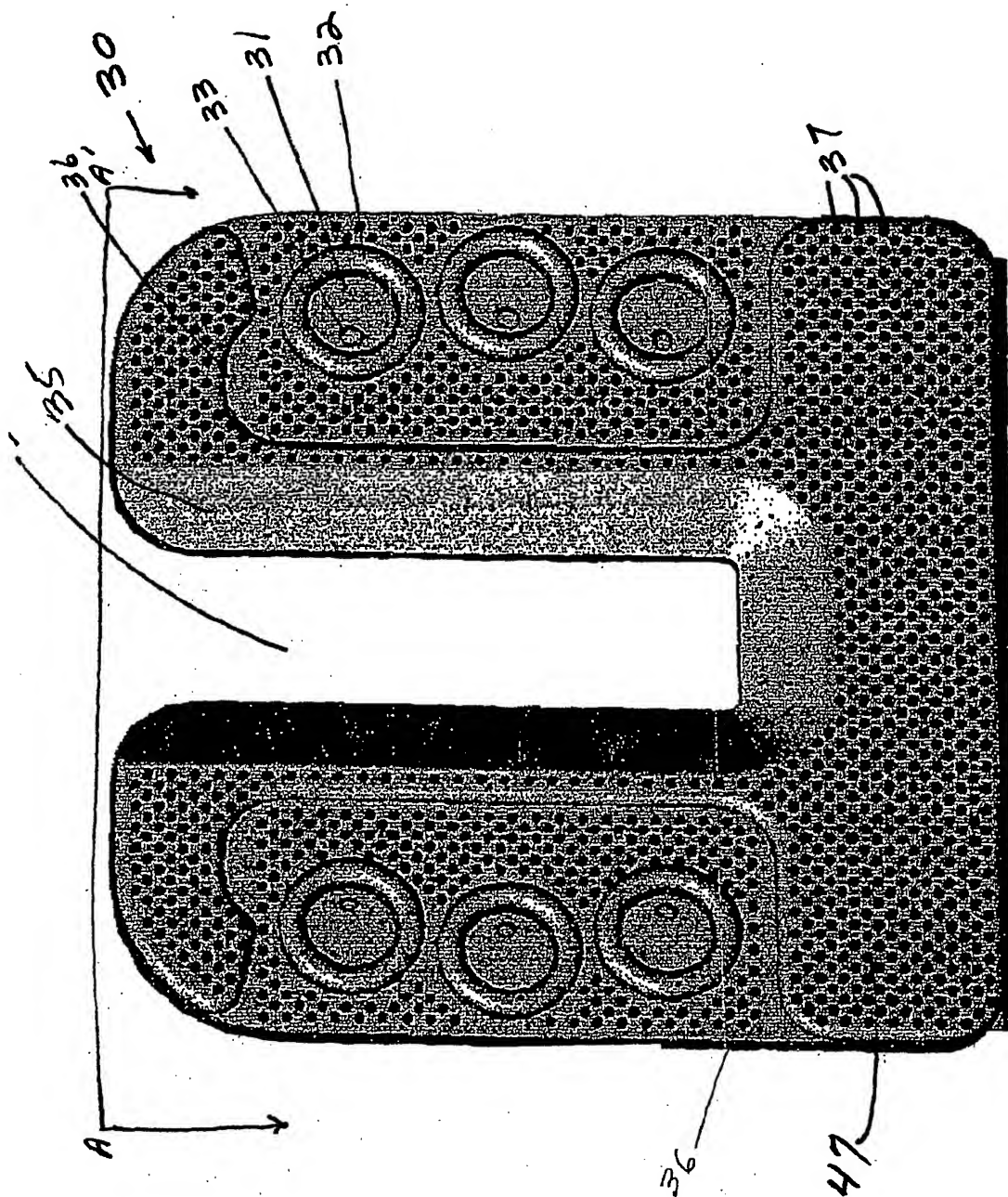


FIG 4

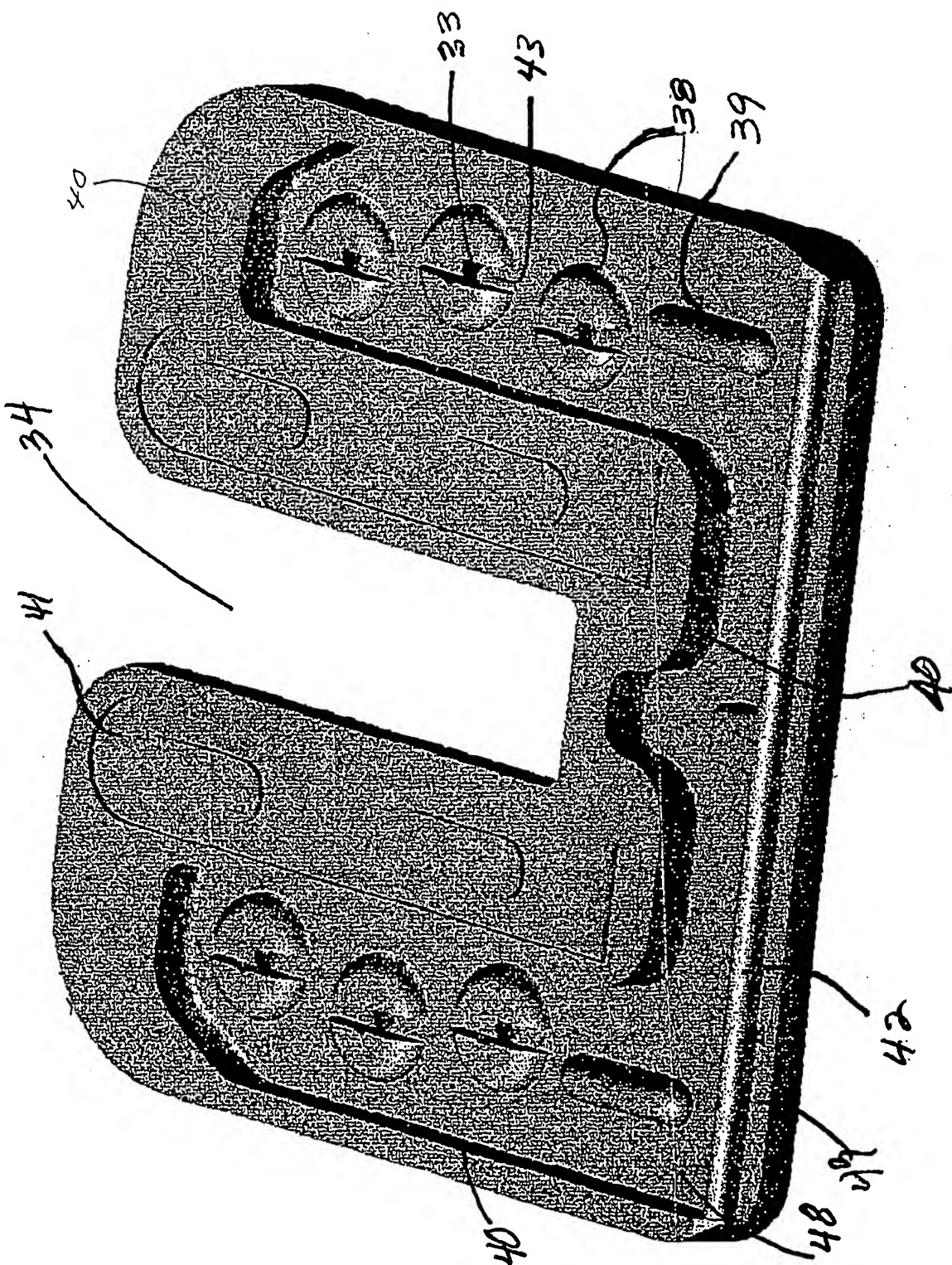
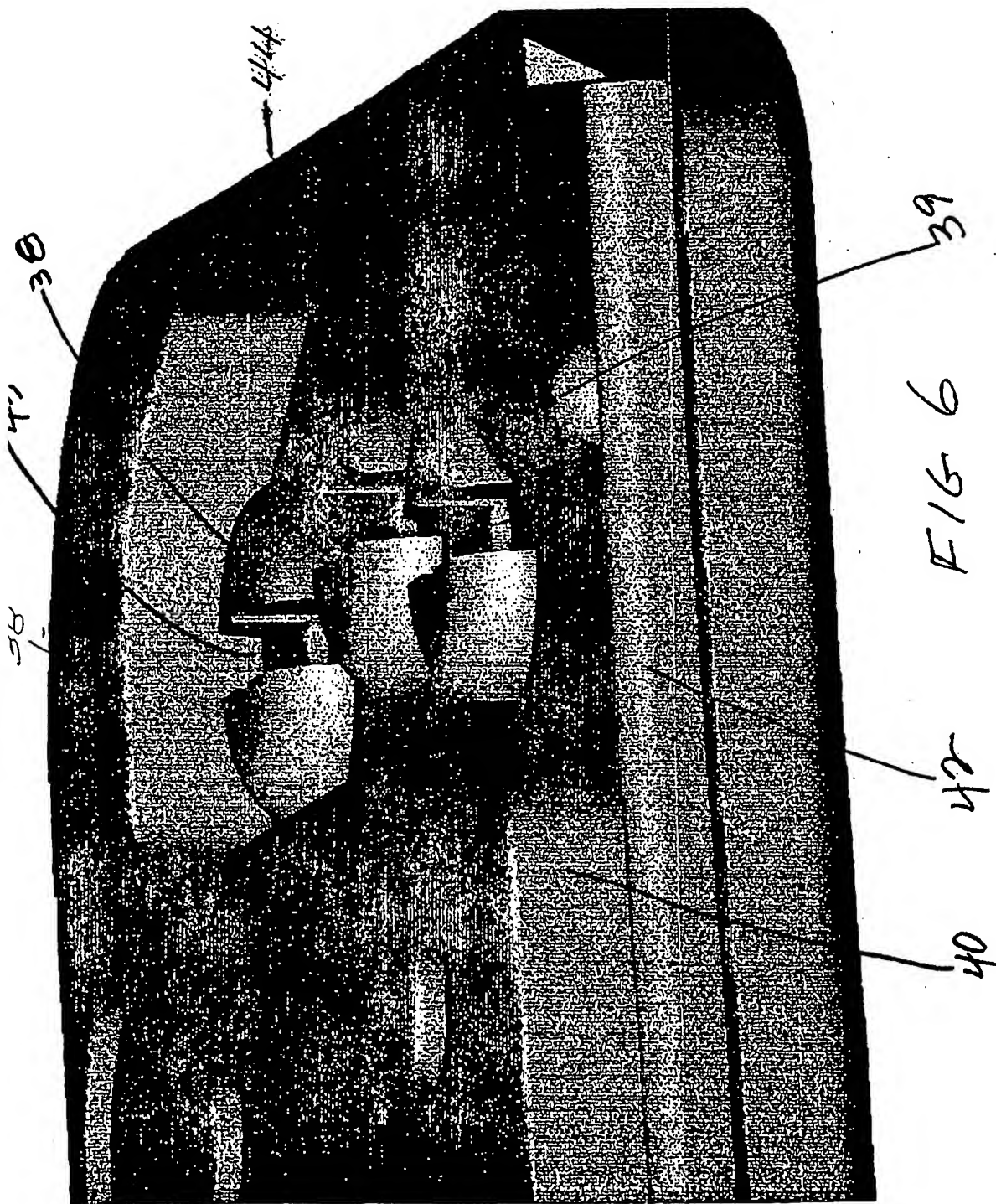


FIG. 5



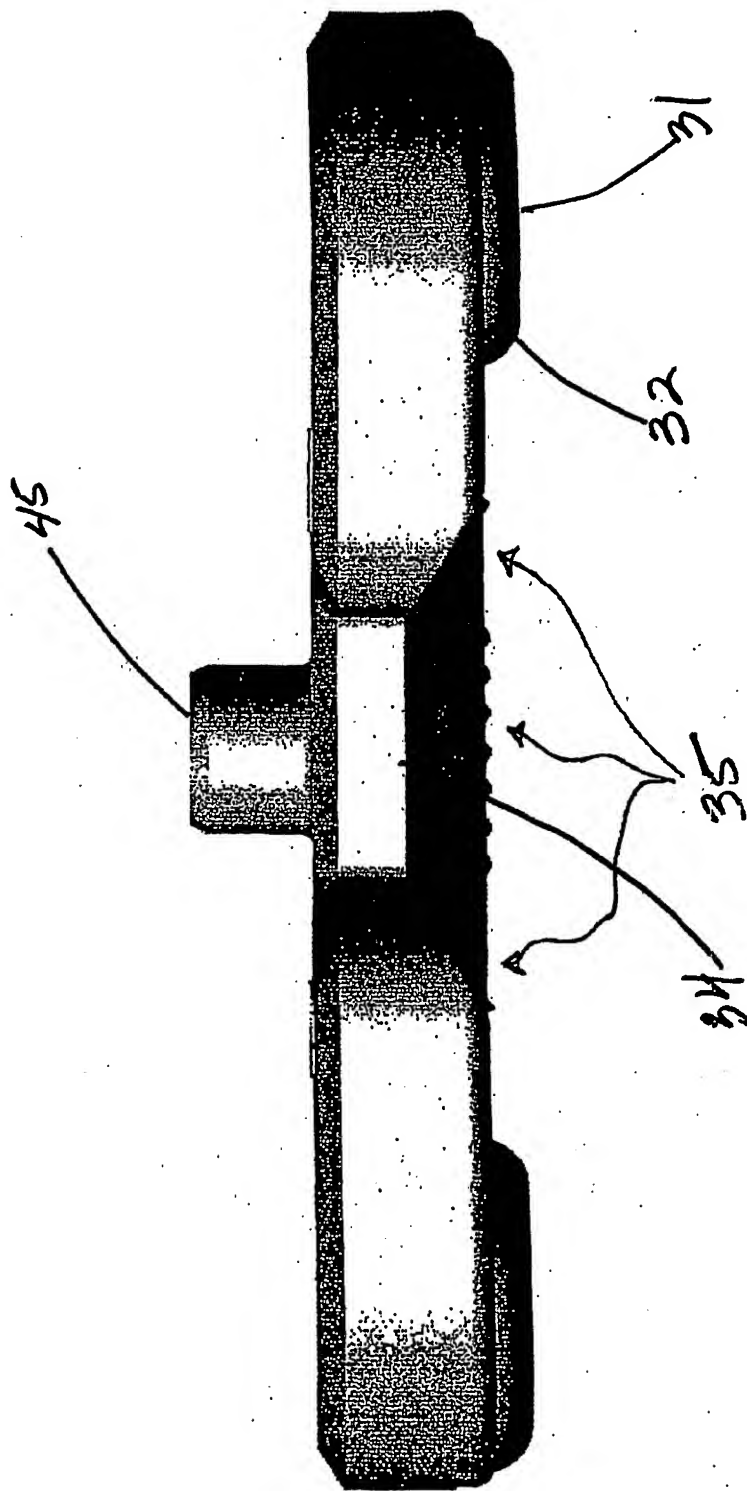
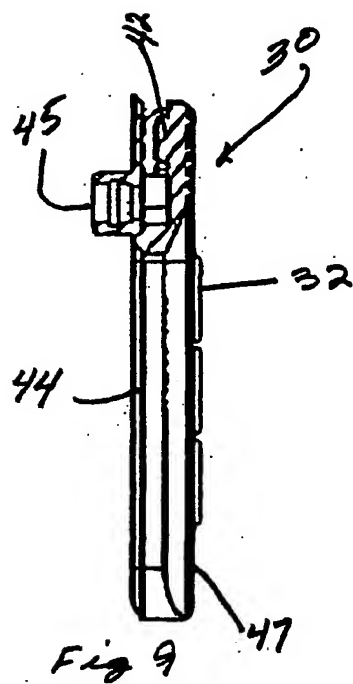
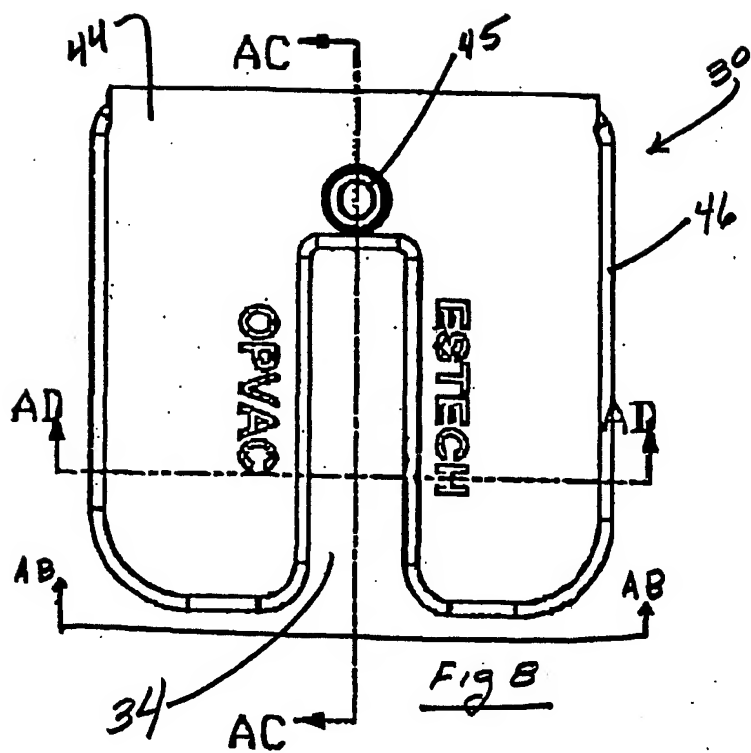
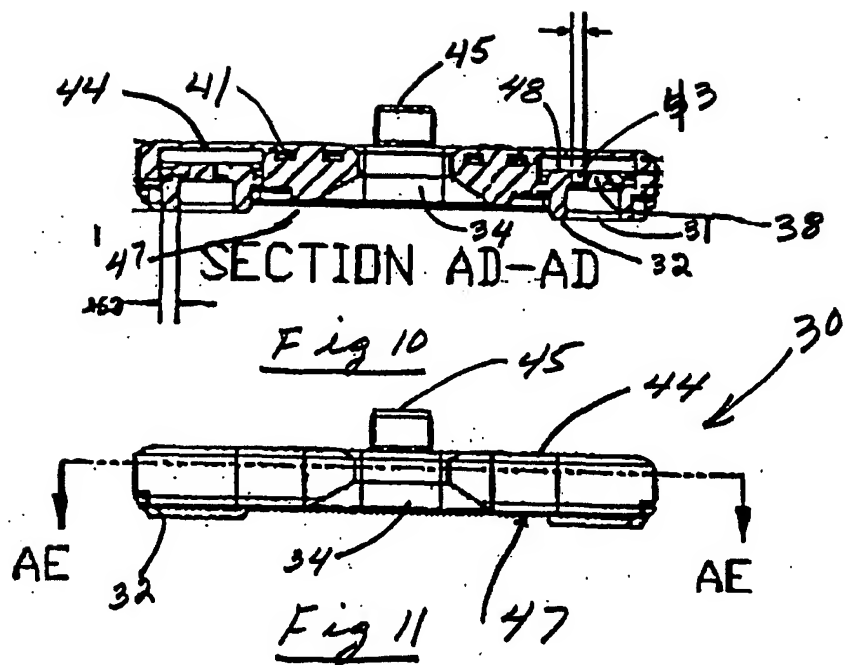


Fig. 7





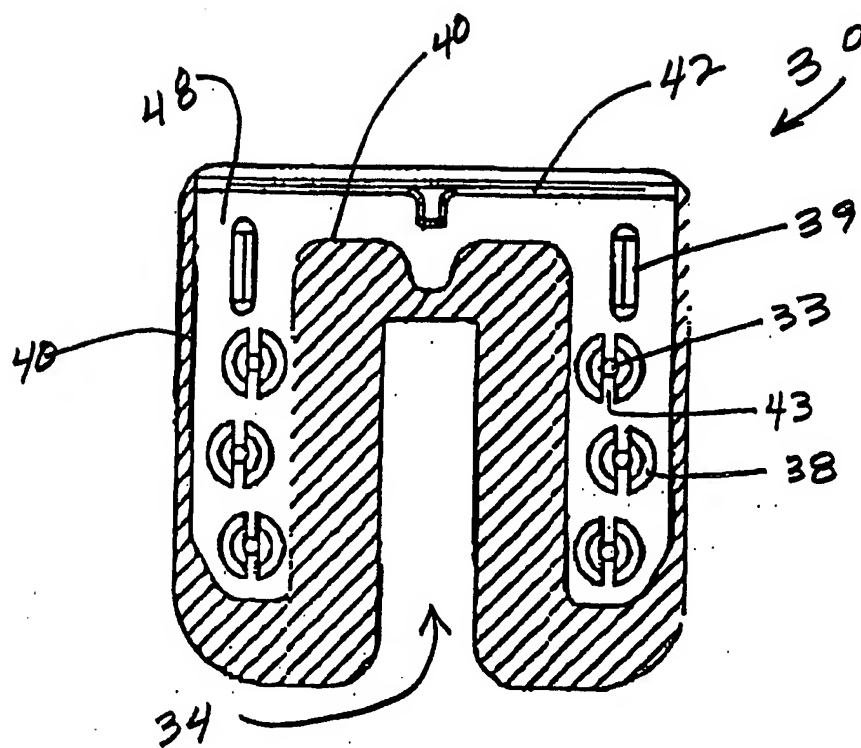
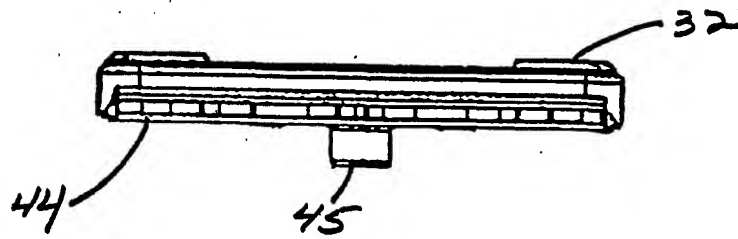
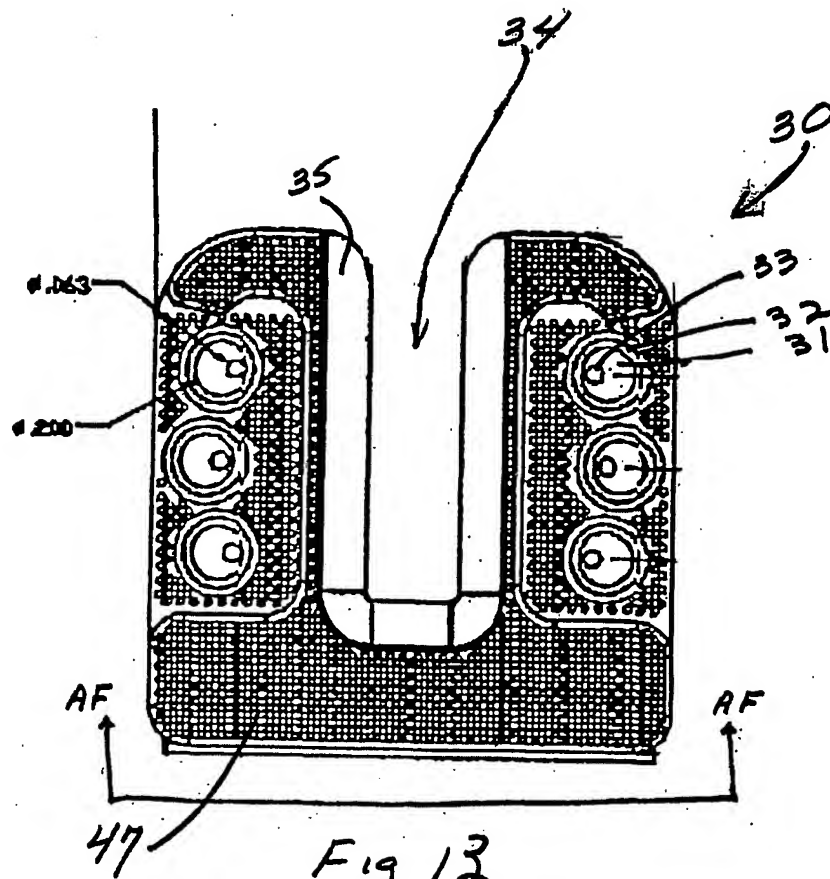
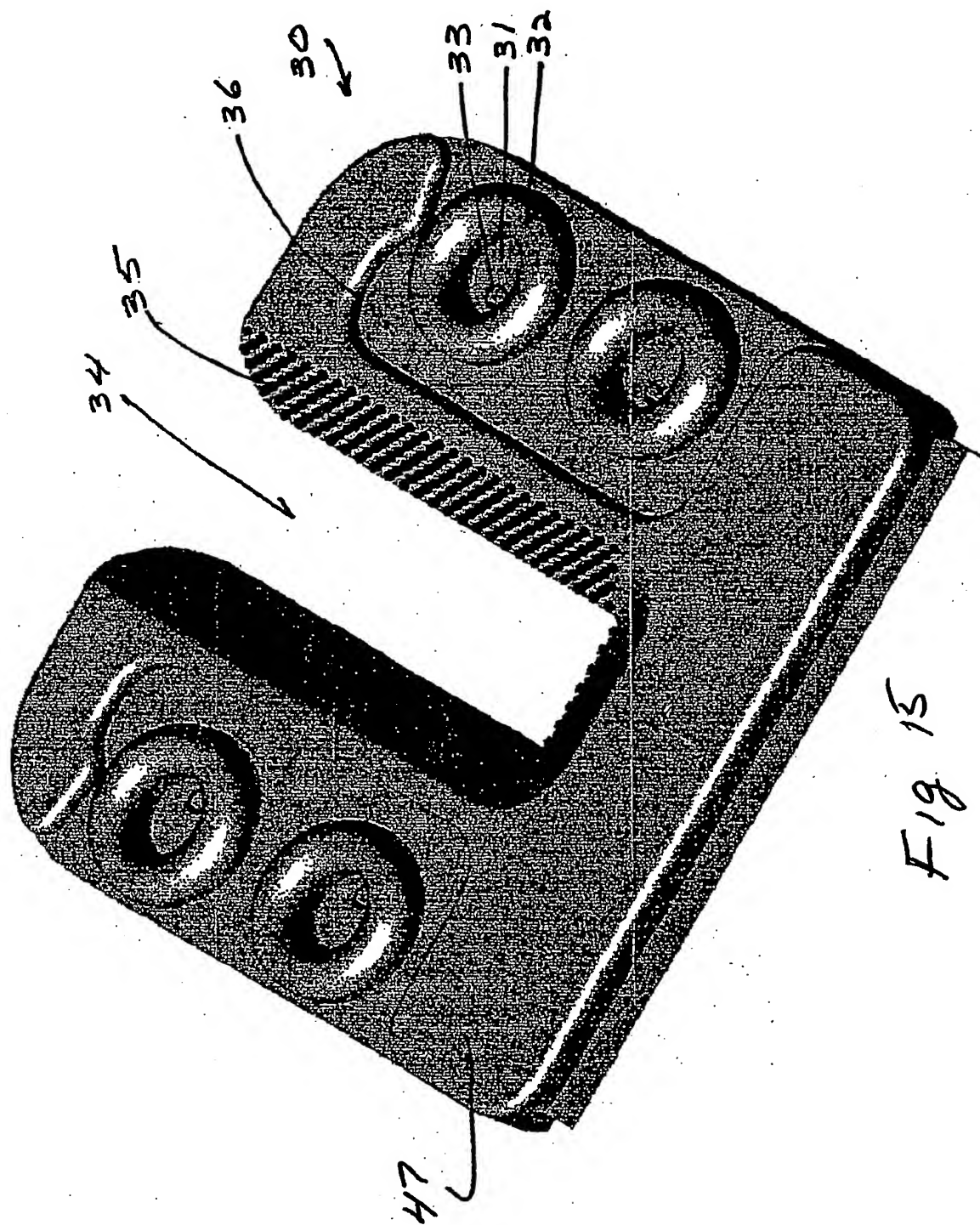


Fig 12





INTERNATIONAL SEARCH REPORT

International Application No

PCT/ . 01/04263

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61B17/02

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 791 329 A (CARDIOTHORACIC SYS INC) 27 August 1997 (1997-08-27)	1,2,7-9, 15,17, 22-24,30
Y	column 8, line 38 -column 9, line 46; figures 6,7,7A,9,9A	3-6,10, 11, 19-21, 25,26
X	US 6 007 486 A (BERKY CRAIG B ET AL) 28 December 1999 (1999-12-28)	42
A	column 3, line 61 -column 4, line 13; figure 1 column 6, line 17 - line 24; figure 10	1,7-11, 15,17, 22-26,30

-/--

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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Date of the actual completion of the international search

27 June 2001

Date of mailing of the international search report

04/07/2001

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INTERNATIONAL SEARCH REPORT

International Application No

PCT/... 01/04263

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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Y	EP 0 791 330 A (CARDIOTHORACIC SYS INC) 27 August 1997 (1997-08-27) column 15, line 46 - line 55; figure 1 column 20, line 14 - line 27; figure 9A column 20, line 53 - line 57; figure 9F abstract; figures 1,2 ----	3-6, 19-21
Y	WO 98 37814 A (TAKAHASHI MASAO) 3 September 1998 (1998-09-03) page 11, paragraph 3; figures 6,8 abstract; figures 1,2,8,9,15,17,23-26,30 -----	10,11, 25,26

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In relation to patent family members

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